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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/890,202	11/05/2001	Stefan Grimm	RDIDO01046US	7800

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EXAMINER

NGUYEN, QUANG

ART UNIT	PAPER NUMBER
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1636

14

DATE MAILED: 10/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/890,202

Applicant(s)

GRIMM ET AL.

Examiner

Quang Nguyen, Ph.D.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 June 2003 and 16 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17-28 and 30 is/are rejected.
- 7) ☒ Claim(s) 29 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### **DETAILED ACTION**

Applicants' amendments filed on 6/12/03 and on 7/16/03 in Paper Nos. 12 and 13 respectively, have been entered.

New claims 17-30 are pending in the present application.

#### ***Response to Amendment***

The art rejections of record are withdrawn in light of Applicants' amendment.

#### ***Specification***

The disclosure is objected to because the specification does not contain subtitle headings (e.g., Background, Brief Description of the Drawings, Detailed Description of the Invention) to conform to standard U.S. patent application.

Appropriate correction is required.

***Following is a new ground of rejection necessitated by Applicants' amendment.***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17-27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a method for isolating and purifying nucleic acids and/or oligonucleotides from a biological sample having the steps recited in claim 17, and a method of transfecting eukaryotic or prokaryotic cells with nucleic acids or oligonucleotides that have been isolated or purified by the same.

The instant specification is not enabled for the methods as claimed for the following reasons.

As written, the claimed methods encompass step (h) or step (a)(8), wherein the nucleic acids and/or oligonucleotides were isolated from a soluble fraction of step (g) or step (a)(7), respectively. However, in step (g) or step (a)(7), the nucleic acids and/or oligonucleotides were bound to the silicon dioxide support material to produce a silicon dioxide bound fraction which is washed at least once with acetone, and therefore little or none of the nucleic acids and/or oligonucleotides remained in the soluble fraction to be isolated and purified. The exemplification clearly showed that plasmid DNA was bound to SiO<sub>2</sub> material support and that the supernatant (or soluble fraction) was discarded (see specification, page 8, section 1.3, lines 23-30, for example).

Since little or none of the nucleic acids and/or oligonucleotides present in the soluble fraction to be isolated and purified, one would not reasonably expect that any

eukaryotic or prokaryotic cells to be transfected by any material recovered from the soluble fraction in the method as claimed.

Accordingly, for the reasons discussed above it would have required undue experimentation for a skilled artisan in the art to make and use the methods as claimed.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al. (U.S. Patent No. 6,297,371; Cited previously) in view of Woodard et al. (U.S. Patent No. 5,693,785).

Colpan et al. disclose a kit containing components necessary for performing a process for the isolation and purification of nucleic acids and/or oligonucleotides for use in gene therapy (col. 7, line 66 continues to line 9 of col. 8), wherein the components include: Buffer P2 (lysis buffer): 200 mM NaOH, 1% SDS; Buffer P3: 3.0M potassium acetate, pH 5.5 (col. 8, lines 20-36); silica materials such as silica gel, diatomaceous earth and others for the preparation of the nucleic acids (col. 6, lines 35-40, and claim 1), isopropanol solution for precipitation (col. 8, lines 59-60).

Colpan et al. do not teach specifically the use of a silicon dioxide support material.

However, at the effective filing date of the present application, Woodard et al. already teach that hydroxylated silicon dioxide-based silica polymers can be used to purify or isolate DNA from aqueous solutions, without the need for the hazardous chemicals previously required as binding reagents for DNA purification (see Summary of the Invention).

Accordingly, it would have been obvious for an ordinary skilled artisan in the art to modify the method or components in the kit taught by Colpan et al., by specifically utilizing hydroxylated silicon dioxide-based silica polymers instead of any silica gel or silica materials because the hydroxylated silicon dioxide-based silica polymers taught by Woodard et al. have been successfully used to purify or isolate DNA from aqueous solutions.

One of ordinary skilled artisan would have been motivated to carry out the above modification because Woodard et al. teach specifically that hydroxylated silicon dioxide-

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based silica polymers can be used to purify or isolate DNA from aqueous solutions, without the need for the hazardous chemicals previously required as binding reagents for DNA purification, and that the isolated DNA can be used directly in subsequent enzymatic processes without concern for the presence of potentially inhibitory substances.

Given the teachings provided by Colpan et al. and Woodard et al., and a high level of skills of an ordinary skilled artisan at the effective filing date of the present application, one of ordinary skilled artisan would have a reasonable expectation of success to practice the presently claimed invention.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

Amended claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Colpan et al. (U.S. Patent No. 6,297,371; Cited previously) in view of Hillebrand et al. (U.S. Patent No. 6,110,363).

The teachings of Colpan et al. have been presented above. Colpan et al. do not teach specifically the use of a silicon dioxide support material.

However, at the effective filing date of the present application, Hillebrand et al. have also taught that DNA is effectively bound to the surface of highly disperse and non-porous solid particles, particularly SiO<sub>2</sub> particles of grain size between 7 and 300 mm and with a specific surface of 10 to 300 m<sup>2</sup>/g (col. 3, lines 9-18), and that SiO<sub>2</sub>

particles have been used as carriers in the isolation and purification of nucleic acids from biological materials.

Accordingly, it would have been obvious for an ordinary skilled artisan in the art to modify the method or components in the kit taught by Colpan et al., by specifically utilizing SiO<sub>2</sub> particles having the characteristics taught by Hillebrand et al. instead of any silica gel or silica materials because these SiO<sub>2</sub> particles have been successfully used in the isolation and purification of nucleic acids from biological materials.

One of ordinary skilled artisan would have been motivated to carry out the above modification because Hillebrand et al. teach specifically that SiO<sub>2</sub> particles that have the disclosed characteristics have been successfully used in the isolation and purification of nucleic acids from biological materials.

Given the teachings provided by Colpan et al. and Hillebrand et al., and a high level of skills of an ordinary skilled artisan at the effective filing date of the present application, one of ordinary skilled artisan would have a reasonable expectation of success to practice the presently claimed invention.

Therefore, the claimed invention as a whole was *prima facie* obvious in the absence of evidence to the contrary.

### **Conclusions**

***No claims are allowable.***



Claim 29 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire **THREE MONTHS** from the date of this action. In the event a first response is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136 (a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (703) 308-1906, or SPE, Irem Yucel, Ph.D., at (703) 305-1998.

Quang Nguyen, Ph.D.

  
DAVID GUZO  
PRIMARY EXAMINER